2013 WL 7208421 (Md.) (Appellate Brief)
Maryland Court of Appeals.

Kevin J. SHANNON, M.D., et al., Petitioners,
v.
Mafalda FUSCO, et al., Respondents.

No. 57.
September Term, 2013.
December 9, 2013.

On appeal from the Court of Special Appeals of Maryland (No.2819, Sept. 2010 Term)

Petitioners' Reply Brief

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***i** TABLE OF CONTENTS

***iii** TABLE OF AUTHORITIES

CASES

*1 PETITIONERS' ARGUMENT IN REPLY

I. The Court of Special Appeals Properly Limited Dr. Trovato's Testimony.

Petitioners wholeheartedly agree with the following aspect of the Court of Special Appeals' opinion: "Dr. Trovato's testimony regarding the nature of the material risks associated with the particular regimen of treatment provided to Mr. Fusco, and any alternative treatment options, would exceed the extent of Dr. Trovato's expertise relative to informed consent." *Fusco v. Shannon*, 210 Md. App. 399, 437-38, 63 A.3d 145 (2013). In this respect, the lower court and intermediate court are in lockstep, as both courts concurred that Dr. Trovato does not possess the experience necessary to opine on these issues given that informed consent is not simply about the medications, it is about a particular patient's condition and the treatment plan tailored to that patient. [E.575-76]. Therefore, a pharmacist is not qualified to give the full demarcation about an informed consent discussion.

Putting aside, momentarily, the fact that Dr. Trovato's remaining testimony was substantively inappropriate given that (a) it pertained to negligence rather than informed consent, and/or (b) the probative value was outweighed by the prejudice of confusing or misleading the jury, the Court of Special Appeals' express limitation on Dr. Trovato's testimony on remand leaves Respondent's case void of the necessary elements of a *prima facie* case of lack of informed consent. In fact, the Court of Special Appeals correctly outlined the elements of the informed consent cause of action in its opinion below:

> "For a complainant to establish a *prima facie* case of failure to obtain informed consent, the complainant must illustrate (1) an existence of a material risk, which the ***physician*** must explain to the patient; (2) the failure of the physician to inform the patient of the ***material risk;*** (3) the physician knew or ought to have known of the ***material risk;*** and (4) a causal connection between the lack of informed consent and the harm."

See Fusco, 210 Md. App. at 411, 63 A.3d at 152 (citations omitted). The intermediate court further acknowledged "[a]n expert witness is required to ascertain the material risks ***2** and other significant factors concerning the medical therapy." *Id.* (citing *Univ. of Maryland Med. Sys. Corp. v. Waldt*, 411 Md. 207, 232, 983 A.2d 112 (2009))(hereinafter *"Waldt II.* Given that Dr. Trovato's testimony was (properly) precluded by the trial court and (properly) limited by the intermediate court, Respondents face the same dispositive void in their case on remand as they did in the primary litigation, and the judgment in Petitioners favor should be affirmed.

Despite this dispositive void, the Court of Special Appeals converted the operative question on appeal to be whether Dr. Trovato was qualified to testify about Amifostine, generally, rather than whether he was qualified to testify about the various requisite elements of a consent discussion pertaining to Amifostine. In deeming he was so qualified, the intermediate court considered Respondents' post-testimonial proffer, and declared that the failure to admit Dr. Trovato's general testimony about the drug (ignoring concerns of relevancy and prejudicial effect) was substantially injurious to Respondents' claim - *despite the fact* that such general testimony was provided by a number of other witnesses and *despite the fact* that Respondents still lacked testimony on the components of an informed consent discussion.

A. While Dr. Trovato May Be Qualified to Testify in the Pharmacy Arena Generally, he is Not Qualified to Discuss Material Risks, Benefits or Alternatives to the Proposed Treatment Regimen.

Respondents correctly deduce that Petitioner's concerns regarding Dr. Trovato's qualifications stem from his lack of education, training and experience in consenting a patient with respect to the material risks, benefits and alternatives to a proposed treatment regimen in an informed consent discussion. These were the same concerns expressed by both the trial court and the Court of Special Appeals when they precluded or limited Dr. Trovato's testimony. Petitioners highlighted the differences in the education, training and experience of Drs. Shannon and Trovato in Brief to this Court, not to disparage the training or knowledge that a pharmacist, like Dr. Trovato, may possess about a drug, but to explicate why Dr. Trovato's pharmacy qualifications do not provide the necessary ***3** foundation to opine on the components of an informed consent discussion relating to a treatment decision involving that drug.

Despite the Court of Special Appeals' clear preclusion of Dr. Trovato's testimony on the elements of lack of informed consent, Respondent's position on the ability of Dr. Trovato to opine on the elements of a lack of informed consent claim is unclear. In certain areas of their Brief, Respondents agree that Dr. Trovato is not qualified to opine on the elements of informed consent (see Resp. Brief, pg. 16, 18); in other areas, however, Respondents state that Dr. Trovato would testify about "known material risks" to Amifostine. (see Resp. Brief, pg 23). [1] Regardless, the Court of Special Appeals clearly maintained that Dr. Trovato lacked the necessary qualifications to provide the jury insight to the material risks, benefits and alternatives to the treatment proposed. The Court of Special Appeals nevertheless held that the lower court's evidentiary rulings constituted clear error by virtue of the fact that the proffer submitted by Respondents (after Dr. Trovato's trial testimony had been secured but shortly prior to the commencement of the actual trial) contained more general information about Amifostine. therapy upon which Dr. Trovato was qualified to testify.

***4 B. A Note about the Court of Special Appeals' Reliance on Respondents' Proffer vice Dr. Trovato's Actual Trial Testimony.**

Before delving into the substantive problems with the Court of Special Appeals' holding, Petitioners would be remiss if they failed to address the concerns regarding the Court of Special Appeals' virtually exclusive reliance upon Respondents' proffer as the factual basis to support its holding. The intermediate court essentially discarded Dr. Trovato's actual trial testimony in favor of the post-testimonial proffer, with no explanation as to why this was warranted. There is something fundamentally flawed about producing a witness for trial testimony (albeit via videotape), which results in opposing counsel zealously and uninhibitedly pursuing their cross-examination of that witness, and then permitting the party who produced the witness to get a "do-over" upon realizing the dispositive voids that very trial testimony left in their case-in-chief. The proffer in this case was not an a priori proffer that trial courts often receive regarding witnesses who have not yet been called, or a proffer requested by the court at the bench to aid in its determination of a ruling for a witness in the midst of testifying. Dr. Trovato's trial testimony was done. Completed. Final. Respondents' proffer contained opinions that counsel failed to elicit during the trial testimony of their expert witness (not to mention opinions that were irrelevant or prejudicial and/or new opinions). For any one of those reasons, the "proffer" should not be considered, and certainly should not have been the sole basis upon which the Court of Special Appeals stripped the verdict from the jury and vacated the judgment in Petitioners' favor. The actual trial testimony of the very witness who is the centerpiece of this appeal was (and is) in-hand, yet the Court of Special Appeals barely gave the de bene esse testimony of Dr. Trovato passing reference when it elected to upheave the rulings made by the trial judge and declare them to be clear error.

If freely granting "do-overs" for trial testimony of witnesses is going to be permissible practice in Maryland courts, then at a minimum, "good cause" should exist for allowing a witness whose trial testimony has already been secured to be permitted to, effectively, be called a second time while simultaneously discarding the prior testimony. ***5** Such conduct is inherently prejudicial to opposing counsel who had diligently and carefully crafted their cross-examination of the witness the first time, and

who properly preserved all requisite objections to render that primary testimony the subject of a (successful) motion in limine. Respondents have no explanation for their need for a do-over, other than to merely concede that "a number of the questions and opinions explored in Dr. Trovato's de bene esse were improper and crossed the boundary into standard of care." See Resp. Brief, pg. 7, fn 1. Respondent's misdirection in their questioning is not good cause; particularly given that Dr. Trovato's trial testimony was in lockstep with his deposition testimony. [E. 139, 151, 156, 158, 160, 161, 402, 403, 405, 406]. Meaning to say, while the case was pleaded on informed consent grounds only, the evidence adduced throughout this case has always sounded in negligence. Thus, the intermediate court's reliance on the proffer in this circumstance, to the virtual exclusion of all else, was improper.

That said, neither Dr. Trovato's trial testimony, nor his proffered testimony salvage Respondents' informed consent claim, as will be discussed further herein. Accordingly, the Court of Special Appeals' reversal of the judgment in Petitioners' favor was erroneous.

C. Dr. Trovato's De Bene Esse Trial Testimony Sounded in Negligence Not Lack of Informed Consent.

As mentioned, Respondents conceded that the questions posed to Dr. Trovato in his trial testimony inappropriately sounded in negligence rather than informed consent. *See* Resp. Brief, pg. 7, fnl. While Respondents claim that there existed some aspects of Dr.Trovato's *de bene esse* testimony that were proper, they did not cite to any page references in the Extract which would support this position. By Petitioners' review of the *de bene esse* testimony, with the exception of Dr. Trovato's recitation of his educational and training background and some isolated areas pertaining to Amifostine generally, Petitioners cannot discern any aspect of the substantive *de bene esse* testimony of Dr. Trovato which would fall within the 'informed consent" domain. Accordingly, the ***6** lower court's preclusion of the *de bene esse* trial testimony of Dr. Trovato, in toto, was proper.

To the extent the Court of Special Appeals opinion is interpreted as remanding the matter to allow minor excerpts from Dr. Trovato's *de bene esse* trial testimony about the properties of Amifostine, generally, (*i.e.*, as a cytoprotective agent), such testimony was provided by at least three other physicians during the course of trial, including Drs. Shannon, Shombert and Boccia. [E.995, 996, 998, 1186, 1189, 1191, 1516]. In short, the jury was not lacking in an understanding of the general properties of Amifostine, the purpose of the drug, and the common side effects; in fact, these basic areas of information about the drug were not in dispute. Accordingly, any error by the lower court in not allowing the few isolated areas of Dr. Trovato's *de bene esse* trial testimony which was unobjectionable to be played to the jury was harmless, as a matter of law.

D. Dr. Trovato's Proffered Testimony was Not Relevant and/or the Probative Value Outweighed the Prejudicial Effect.

To the extent that this Court likewise relies upon the proffer as opposed to the actual trial testimony, the proffer contained opinions which were either not relevant or whose probative value was outweighed by the prejudicial effect. For example, Dr. Trovato was proffered to discuss all potential adverse reactions to Amifostine. These opinions are both irrelevant and misleading. First and foremost, as the trial court correctly noted, Dr. Trovato "doesn't testify as to what the material risks are. And that gets to the meat of it. There are risks in everything. I walk out here and walk down the step, I could trip on my robe. That's a risk, but it's not a material risk." [E.550]. As the lower court stated, the fact that risks may exist is not relevant in an informed consent case, the pertinent question is whether those risks were material to the treatment proposed and thus, warranted disclosure by Petitioners. *Id.*

In the context of discussing a physician's duty in an informed consent action, this Court has likewise affirmed that Maryland law adheres to the principle that a physician is not obligated to disclose risks that are infintesimal. See ***7** McQuitty v. Spangler, 410 Md. 1, 12, 976 A.2d 1020, 1032 (2009)(stating that a healthcare provider is not burdened with the duty of divulging all risks, but only those which are material to the intelligent decision of a reasonably prudent patient)(internal citations omitted). This well-established principle goes to the crux of the lower court's ruling in this case and underscores why the intermediate

court's ruling to the contrary is flawed. As it relates to the specific issue/injury in this case, Respondents proffered that Dr. Trovato would testify that Stevens Johnson Syndrome (SJS) is one of the potential adverse reactions from Amifostine. Notably, it is undisputed that the risk of SJS or TENS from Amifostine is between 6-9 cases per 10,000, for a statistical rate of 0.06 to 0.09. [E.1531-33, 1547-48]. As a result, the rare condition of SJS is not considered a material risk to Amifostine and is not routinely discussed with patients during informed consent discussions. [E.1438, 1510].

1. The applicable standard for "material risks" in lack of informed consent cases.

Nevertheless, Respondents maintain that the jury should be permitted to hear testimony about virtually any potential adverse effect from the drug and the jury should determine which of those risks is "material" and which should be disclosed by the physician to the patient.[2] Petitioners disagree. A physician's decision about the requisite disclosures for informed consent should be well-grounded in medical science, the medical literature, and the standards of medical practice. Removing such determinations from the medical community, as Respondents urge this Court to do, and placing those determinations in the hands of laypersons is inconsistent with Maryland law, unfair to Maryland physicians, and a poor public policy decision. What six people decide is "material" as it relates to Amifostine in one trial could be completely different from what six people in the courtroom next door decide is "material." The manner in which a physician provides medical care to a patient should be dictated by sound medical science, not the *ex post facto* whims of empaneled jurors in one given malpractice trial. A ***8** physician would have no way of measuring, a priori, his/her compliance with informed consent requirements. Even if a physician thoroughly divulges what the medical community universally deems to be the material risks of a proposed treatment, a patient may be struck with some obscure and rare reaction (as in this case, with the statistical odds of acquiring SJS/TENS being far less than one-tenth of one percent), and a physician could be held liable for lack of informed consent per Respondent's proposed standard.

Furthermore, ensuring that the information disclosed by a physician is consistent with sound medical science (in terms of what constitutes a material risk, benefit or alternative to a procedure) does not remove informed consent law in Maryland from a patient-centric approach. To the contrary, the jury must still determine whether "a reasonable patient, having been provided proper informed consent, would have withheld consent to the proposed treatment." An informed consent claim is a two-step process for the jury, requiring consideration of (a) whether the material risks, etc., to a particular treatment were disclosed, and (b) whether a reasonable patient would have withheld consent upon being informed of the material risks, etc. to a particular treatment. This second component of a jury's determination in an informed consent case is purely a patient-centric general reasonableness standard, and does not require (or even permit) expert testimony. Respondents, on the other hand, maintain that both elements of an informed consent claim should be determined by a "reasonableness" standard, not a "professional" standard. Petitioners respectfully disagree that the material risks of a particular treatment should be left to the caprices of the jury.[3]

9** Maryland courts, in cases subsequent to *Sard v. Hardy*, 281 Md. 432, 379 A.2d 1014 (1977), have continued to explicate the scope of a physician's duty in informed consent cases to that which a ***physician knows or ought to know would be significant to a reasonable patient. See McQuitty, 410 Md. at 21, 976 A.2d at 1032; *Zeller v. Greater Baltimore Med. Center*, 67 Md. App. 75, 84, 506 A.2d 646, 651 (1986). Thus, "material risks" is the fundamental question in establishing duty in an informed consent claim, the scope of which is defined as ***that which a physician knows or ought to know.*** Furthermore, this Court has made clear "expert testimony is necessary to establish the material risks and other pertinent information regarding the treatment or procedure." *Wallt*, 411 Md. at 232, 983 A.2d at 127. The Legislature likewise determined that a professional standard would be applicable for any claim for medical injury, including lack of informed consent. Section 3-2A-02(c)(1) provides that: "In any action for damages filed under this subtitle, the health care provider is not liable for the payment of damages unless it is established that the care given by the health care provider is not in accordance with the standards of practice among members of the same health care profession with similar training and experience situated in the same or similar communities at the time of the alleged act giving rise to the cause of action." See §3-2A-02(c)(1), Md. Cts. & Jud. Pro. ART. While informed consent actions are expressly excluded from the requirement that a Certificate of Qualified Expert be submitted pursuant to Section 3-2A-04, informed consent actions are not excluded from the requirements for establishment of liability, generally. Thus, there

has been, is, and should continue to be a professional standard to which physicians are held as it pertains to the materiality of risks and other pertinent information about a proposed treatment for informed consent disclosures. [4]

***10** The fact that Maryland adopted a "reasonable person" standard for the ulitmate determination of whether a patient would have declined treatment had all the material risks been disclosed, does not mean that Maryland has abandoned all elements of medical custom, practice and science in determining the substance of the required disclosure. To the contrary, Maryland courts have routinely stated that when it comes to adducing evidence of what constitutes "material risks" - expert testimony is required. [5] *See e.g. Waldt*, 411 Md. at 232, 983 A.2d at 127.

2. The components of an informed consent discussion.

Incidentally, Respondents argued that Petitioners use of "material risks" was inappropriately limiting in terms of defining what is necessary in an informed consent discussion. See Resp. Brief, pg. 34. Petitioners are well-aware that informed consent doctrine encompasses more than just "material risks," it includes "other pertinent information regarding a proposed treatment," such as the benefits to the treatment and alternatives to the treatment. See Waldt, 411 Md. at 232. That said, Dr. Trovato provided none of the aforementioned requisite substantive testimony at trial; in fact, his trial testimony was that use of the drug was improper in the **elderly** and for prostate ***11** cancer patients. [E.151,156,158,160, 161]. Furthermore, Dr. Trovato, is not qualified to testify about any aspects of an informed consent discussion (per the Court of Special Appeals' holding) on remand. [6] To the extent the proffer outlines information about Amifostine, generally, that information was sufficient addressed by other experts, and thus, any error is harmless.

E. Summary Judgment and/or Judgment in Petitioners' Favor was Mandated as a Matter of Law.

Respondents' only argument to counter the fact that summary judgment and judgment were warranted below is their belief that Maryland does not require expert testimony and/or a professional standard for lack of informed consent and instead, permits material risks to be determined by a jury using a general reasonableness standard, which, again, Respondents insist is "independent of medical custom." See Resp. Brief, pg. 39-40. Respondents claim that the information that a physician must impart is "not defined by the medical community." *Id.* In so doing, Respondents ignore Maryland cases which have defined the physician's duty in informed consent cases to that which a physician knows or ought to know would be significant to a reasonable patient. *See McQuitty*, 410 Md. at 21, 976 A.2d at 1032; *Zeller*, 67 Md. App. at 84, 506 A.2d at 651. As discussed supra, duty in an informed consent claim is grounded in "material risks," the scope of which is defined as **that which a physician knows or ought to know.** This Court has made clear **"expert testimony is necessary to establish the material risks** and ***12** other pertinent information regarding the treatment or procedure." Waldt, 411 Md. at 232, 983 A.2d at 127.

The Court of Special Appeals likewise correctly noted that "an expert witness is required to ascertain the material risks and other significant factors concerning the medical therapy." Fusco, 210 Md. App. at 411, 63 A.3d at 152. In short, there is no dispute among either the lower court, the Court of Special Appeals, nor precedent from this Court that expert testimony is "necessary to establish the material risks and other pertinent information regarding the treatment or procedure." Respondents' claim that Maryland has dispensed with a professional standard as it relates to that which constitutes a material risk and other pertinent information regarding a proposed treatment is incorrect. Respondents provide no additional grounds upon which Petitioners' argument for summary judgment / judgment can be defeated. Therefore, upon consideration of (and affirmation of) the need for expert testimony in a complex case like this, coupled with Respondents' clear lack of that requisite expert testimony, it is clear that judgment in Petitioners' favor should have been granted below and should be reinstated on appeal.

Respondents produced no expert testimony on the issue of material risks to Amifostine. No expert testified that TENS was a material risk to Amifostine; no expert testified that Stevens Johnson Syndrome was a material risk to Amifostine; no expert testified that off-label use was a material risk to Amifostine; no expert testified that limited clinical trials on prostate cancer or **elderly** patients was a material risk to Amifostine. On every level conceivable, Respondents' failed to establish a prima facie

case of lack of informed consent. Even if this Court somehow affirms the intermediate court and allows the pharmacist to testify to Amifostine, generally.,Dr. Trovato cannot offer any opinions as to that which constituted a "material risk" of Amifostine requiring disclosure by Dr. Shannon in order to satisfy the doctrine of informed consent. Dr. Trovato never rendered those opinions in his deposition, nor in his de bene esse videotaped trial testimony, nor in his proffer. The lack of evidence on "material risks" ***13** was a dispositive gap in Respondents' case below, and will continue to be a dispositive gap upon remand.

F. Any Error by the Trial Court was Harmless, as a Matter of Law.

In summary, the trial court's determination that Dr. Trovato's opinions lacked probative value and were otherwise outweighed by the prejudicial effect was correct.[7] After reviewing the pleadings, conducting two separate hearings on the matter, reading the deposition testimony of Dr. Trovato, the de bene esse of Dr. Trovato, the proffer by Respondents' counsel and multiple cases from our appellate courts, Judge Green found that Dr. Trovato's testimony gave "*great indifference to relevance to the issue at hand.* That is informed consent." [E.558-59]. First, the lower court emphasized that Dr. Trovato's testimony is more in line with negligence than that of informed consent." *Id.* Second, the court noted that testimony by a pharmacist about the existence of risks does not equate to "material risks" for purposes of an informed consent discussion and would only serve to confuse the issues, mislead the jury and cause unfair prejudice to Petitioners. See Md. Rule 5-403. Finally, the lower court determined (and Court of Special Appeals' affirmed) that Dr. Trovato lacked the necessary expertise to opine on the material risks, benefits or alternatives to the proposed treatment regimen of Amifostine. These rulings were correct and well within the court's broad discretion in determining the propriety of expert witness testimony.

***14** To the extent that this Court finds some concurrence with the intermediate court's opinion that Dr. Trovato should have been permitted to testify generally about the properties of Amifostine and its common side effects, the error in precluding Dr. Trovato's limited testimony is necessarily harmless. First, even on remand Dr. Trovato is not authorized/qualified to testify about material risks or other pertinent information required in an informed consent discussion. Accordingly, Dr. Trovato's testimony, while providing general information about the drug, would not and could not change the jury's consideration of the elements of an informed consent claim. To decide upon an informed consent cause of action, the jury needs to understand not merely the general properties of Amifostine, but the role the drug played in the treatment decisions for the patient, and the material risks, benefits, alternatives to the drug, for which even the intermediate court agreed Dr. Trovato was not qualified to discuss.

Second, the testimony about which Dr. Trovato is qualified to testify, i.e. Amifostine, generally, was covered by several witnesses at this trial, and therefore, the jury was not for want of information on Amifostine. Ironically, in attempting to argue that the lower court properly denied judgment in Petitioner's favor at the close of Respondent's case and at the close of evidence, Respondent concedes that they obtained sufficient testimony about Amifostine and the side effects of Amifostine, including skin reactions, from Dr. Shannon, Dr. Shombert, and Dr. Boccia's testimony. [E.995, 996, 998, 1186, 1189, 1191, 1531-33]. Thus, while Dr. Trovato may be qualified to testify about Amifostine, generally, the jury was not lacking in the limited information on Amifostine he would provide. Accordingly, even if this Court determines that a blanket exclusion of Dr. Trovato was inappropriate, that exclusion was harmless error.

Third, the jury was clearly aware that Mr. Fusco acquired SJS/TENS. Even if the jury disagreed on the information that Dr. Shannon was required to disclose, the jury unanimously agreed that a reasonable person wouldn't refuse consent based upon any implied nondisclosure of SJS/TENS (most likely due to the infinitesimal risk (0.06) associated with SJS and TENS).

***15** For these reasons, regardless of the conclusion drawn by the Court of Special Appeals as to limited admissibility of Dr. Trovato's testimony, the harmless error analysis alone should have resulted in an affirmance of the judgment below. Therefore, even if this Court elects to agree, chapter and verse, with the intermediate court on its various evidentiary determinations, the basic tenets of appellate jurisprudence demand consideration of harmless error analysis before stripping a verdict from the jury and remanding for a new trial. Manifest error and substantial injury are required, but clearly are not present in this case.

II. The Trial Court's Evidentiary Rulings Regarding the Package Insert and FDA Approval Were Proper.

A. The Package Insert's Precautionary Statement that there had been Limited Clinical Trials Involving Elderly Patients was Properly Excluded by the Trial Court.

It is noteworthy that Respondents' do not dispute that Dr. Trovato only raised the package insert's precautionary statements regarding the limited testing in the **elderly** as support for his opinions that the use of Amifostine was inappropriate, i.e., a basis for his opinions sounding in negligence. [E.158-59, 160, 161] Respondents never adduced any evidence in discovery that the limited testing in the **elderly** was a material risk to Amifostine which Dr. Shannon needed to disclose to obtain informed consent. Likewise, Dr. Trovato's trial testimony never included opinions that limited testing in the **elderly** was a material risk requiring disclosure. In fact, even Respondents' untimely post-discovery proffer failed to contend that the lack of testing in the **elderly** was a material risk to the drug. [E.488] The proffer merely stated that Dr. Trovato will testify that the package insert gives a precaution as to the administration (i.e., use) of the drug to the **elderly** since the effects have not been tested extensively in the **elderly** population. [E.488]. In that manner, the proffer continues to sound in negligence and not informed consent. *Id.*

***16** Furthermore, Respondents sought to utilize a (post-dated) package insert [8] from a (different) manufacturer of Amifostine and read the myriad of listed possible adverse reactions (hearsay). Putting aside the problems with the package insert itself, for the moment, Dr. Trovato never identified the risks were material to an informed consent discussion with a patient; i.e., the risks that a physician knows or ought to know would be *material* to a patient's decision. The fact that a myriad of possible adverse reactions may exist does not mean that Dr. Shannon had a *duty to disclose* each and every one of those risks to Mr. Fusco. Respondents never adduced the requisite evidence that Dr. Shannon needed to disclose material risk "x" or material risk "y" to constitute informed consent. In short, a precautionary note that there had been limited testing of the drug in the **elderly** equates to a "so what?" without further testimony holding that such limited testing creates a material risk to the drug in this particular patient and therefore is a necessary component of an informed consent discussion. Limited testing in a particular population could be due to a myriad of reasons, none of which create a higher risk of any adverse reaction in Mr. Fusco. Furthermore, there was no testimony, whatsoever, in this case that limited testing in the **elderly** population held any causal relationship to the outcome, i.e., that it was the reason Mr. Fusco ended up with SJS/TENS. *See e.g. Lipscomb v.* ***17** *Memorial Hospital,* 733 F.2d 332, 338 (4th Cir. 1984)(applying Maryland law). Accordingly, the intermediate court's holding effectively forces the introduction of testimony on remand that is without probative value, given the lack of testimony declaring the limited testing in the **elderly** to be a material risk. See Md. Rule 5-402. Furthermore, any probative value in this information is greatly outweighed by the prejudicial effect of confusing and misleading the jury. See Md. Rule 5-403. Accordingly, the trial court's preclusion of the package insert was entirely appropriate, well supported by the rules of evidence and well within its broad discretionary authority for evidentiary rulings. [9] The Court of Special Appeals' reversal of the judgment in favor of Petitioners on this basis is unfounded.

***18** To the extent this Court finds error in precluding the package insert or its precaution about limited testing in the **elderly** population, such error is harmless as a matter of law. First, Dr. Trovato's testimony (and proffer) only linked the limited testing in the **elderly** to the propriety of using the drug. Second, Dr. Trovato's testimony (and proffer) never espoused that notifying Mr. Fusco of the limited testing in the **elderly** was a required component of informed consent for a proposed treatment, and along those lines, given that Dr. Trovato is precluded from offering such testimony on remand, any error in precluding this testimony below was neither "manifestly wrong and substantially injurious." *See Beahm v. Shortall,* 279 Md. 321, 331, 368 A.2d 1005, 1011 (1977). The conclusion of the Court of Special Appeals to the contrary is erroneous; the judgment of the intermediate court should be reversed and the judgment of the lower court reinstated.

B. Evidence Regarding the Lack of FDA Approval of the Drug Specific to Prostate Cancer was Properly Excluded by the Trial Court.

1. This Case Lacks the Necessary Factual Predicate to Support a Departure from *Waldt II*.

As previously discussed, Dr. Trovato's testimony throughout discovery and de bene esse trial testimony was that the use of Amifostine was inappropriate in this case. One of the bases for his opinion that it was wrong to use Amifostine in Mr. Fusco's care was that the FDA had not specifically approved Amifostine in prostate cancer patients. [E.151,156]. [10] Even Respondent's "proffer" only provided that the status of the FDA clinical trials for Amifostine's use in prostate cancer patients do not demonstrate the "efficacy of Amifostine." [E.486]. Once again, Dr. Trovato's opinions in this regard sounded in negligence and not lack of informed consent. Petitioners objected to the introduction of evidence of FDA approval, not only on the grounds that Respondents' claims sounded in negligence as opposed to informed consent, but also on the basis that Maryland case law established that the approval, or lack thereof, by the FDA of a ***19** particular drug or product was relevant to a negligence claim, not a lack of informed consent claim. *See University of Maryland Medical System v. Waldt,* 411 Md. 207, 983 A.2d 112 (2009)(*Waldt II*).

Before delving to the Respondents' incorrect analysis of *Waldt II,* it is important to emphasize the complete lack of factual foundation for the position espoused by the Court of Special Appeals on the FDA issue. Kindly allow Petitioners to restate the following: Respondents adduced *no evidence* in discovery, de bene esse trial testimony, nor in the post-testimonial proffer that the FDA status was a material risk to the treatment regimen proposed, or even a necessary component of an informed consent discussion, generally. [11] Curiously, despite the complete lack of factual predicate for its holding on the FDA issue, the Court of Special Appeals deemed the trial court's preclusion of the same to be reversible error. On remand, one of two things must occur: either (a) Dr. Trovato will offer new opinions that were not previously disclosed, to wit: the fact that the FDA has approved Amifostine for head, neck and kidney cancer, but not yet prostate, is a required component of an informed consent discussion with a patient (even though the Court of Special Appeals' own holding precludes Dr. Trovato from offering testimony on components of an informed consent discussion); or (b) the trial court will be forced to ignore the basic rules of evidence and permit otherwise irrelevant and/or confusing and misleading testimony before the jury. See Md. Rule 5-403. Thus, the Court of Special Appeals holding requires either a violation of the discovery rules, a disregard for its own holding limiting Dr. Trovato's testimony, or discounting the most fundamental rule of ***20** evidence: relevance. [12] The fact that this quagmire would be the end result of the Court of Special Appeals' opinion demonstrates how imperative review by this Court's was.

Without the necessary factual predicate, appellate courts cannot strip a verdict from the jury. Perhaps the Court of Special Appeals believes that informed consent law should encompass disclosures about status updates of FDA clinical trials; perhaps this Court believes the same. Regardless of that belief, appellate courts cannot create these laws in the absence of a factual predicate below. Even if this Court firmly believes that its holding in *Waldt II* should not preclude future informed consent claims from raising an FDA issue, *this is not the case on which to base that principle.* There is no predicate for Respondent's position on these facts; there is no predicate for Respondent's position in this case.

2. *Waldt II* is Both Analogous and Controlling.

Respondents attempt to distinguish (or otherwise downplay) this Court's holding in *Waldt II* that testimony regarding the FDA approval "would be relevant to an ordinary negligence claim, i.e., that the doctors breached the standard of care in their treatment of Mrs. Waldt by performing a contraindicated procedure on her. **It is not relevant to an informed consent claim."** *Id.* at 236 (emphasis added). First, Respondents claim that their "proffer" was much more extensive than the proffer submitted in *Waldt II,* and because this Court commented that a sufficient proffer in *Waldt II* had not been made, the proffered testimony by Respondent should have been considered sufficient and thus, admissible. [13] To the contrary, while Respondents' proffer was longer than Waldt II, ***21** their proffer is still ripe with problems. The proffer still sounds in negligence as opposed to lack of informed consent, and therefore, remains as "insufficien" as the Waldt II proffer. Furthermore, to the extent that the proffer can be interpreted as containing "informed consent-type" opinions, then (a) those would be new opinion not previously disclosed

in discovery and (b) those would be impermissible areas of testimony for Dr. Trovato per the Court of Special Appeals' express holding.

Second, Respondents attempt to argue that the *Waldt II* Court's exclusion of the FDA approval issue was due to the *Waldt II* expert's lack of qualifications and not that the FDA approval issue was irrelevant to the informed consent claim. This is incorrect. While the *Waldt II* Court certainly discussed the expert's lack of qualifications, it addressed the question of relevancy of the proffered testimony independently, before weighing in on the expert's lack of qualifications. *Id.* at 235-35. After holding that "no testimony was proffered concerning the material risks of the procedure that would make out a prima facie case for informed consent," *see id.* at 236, this Court went on to state, "[i]n addition, it is within the discretion of the trial judge to qualify witnesses as experts," and then discussed the expert's lack of qualifications. Despite Respondents' best efforts; they cannot get away from the clear holding in *Waldt II*, that the issue of FDA-approved uses of the drug goes more toward the propriety of using the drug (negligence) than to claims of lack of informed consent.

Again, on these facts, Respondents do not have the requisite testimony (or proffer) that FDA approval status was a material risk to the use of drug or was required disclosure in an informed consent discussion. If this Court elects to adopt that position, then it should do so in a future case wherein a plaintiff has adduced evidence from a duly qualified expert that FDA approval is a material risk to drug and a necessary disclosure in an informed consent discussion. Respondents simply do not have the requisite factual ***22** foundation to support such a position here. The lower court's preclusion of this evidence was proper, and the Court of Special Appeals reversal therein was erroneous. Petitioners request that this Court reverse the judgment of the intermediate court and reinstate the judgment in Petitioners favor entered by the lower court.

3. Extrajursidctional authority and sound public policy reasons overwhelmingly support the stance this Court took in Waldt II, that FDA approval should not be a mandatory requirement of an informed consent discussion.

It is noteworthy that Respondents provided no response or counter to the overwhelming extrajurisdictional authority which supports the principle that the FDA status of a particular drug or treatment should not be a required component of an informed consent discussion. The majority position holds that "the category into which the FDA places the device for marketing and labeling purposes simply does not enlighten the patient as to the nature or seriousness of the proposed operation, the organs of the body involved, the disease sought to be cured, or the possible results. The FDA administrative label does not constitute a material fact, risk, complication or alternative to a surgical procedure. It follows that a physician need not disclose a device's FDA classification to the patient in order to ensure that the patient has been fully informed regarding the procedure." See Southard v. Temple University Hosp., 781 A.2d 101, 107 (Pa. 2001). See also Blazoski v. Cook, 787 A.2d 910, 919 (N.J. Super. App. Div. 2002)(noting that "the FDA regulatory status does not speak directly to the medical issues surrounding a particular [treatment]" and that the "FDA's concern is to regulate the marketing and labeling of medical drugs and devices, not to intrude upon the practice of medicine or redefine the doctrine of informed consent"). To the extent this Court considers the issue of whether FDA status is a required component of an informed consent discussion (despite the lack of factual predicate in this case), Petitioners maintain that the majority view, as espoused in our sister states, supra, is consistent with Maryland law and promotes sensible public policy.

***23** Petitioners further note that the Brief of Amici Curie discusses in greater detail (than the page limitations afford Petitioners) the overwhelming support for this Court's position in *Waldt II*, not only in the medical literature and by respected medical societies such as the American Medical Association, but by the majority of other states which have considered this issue. Petitioners adopt and incorporate the Amici arguments which advance the position that the regulatory status of a drug (or its product label) bears no relation to the actual material risks of a proposed medical treatment, and in fact, will mislead, confuse and confound patients from a true understanding of the actual risks of the treatment. See Amici, generally, pgs. 36-40.

Requiring physicians to keep abreast of the regulatory status of each drug and each device produced by the myriad of pharmaceutical companies in existence is grossly burdensome to physicians and serves an end that provides little, if any, value to the patient. The regulatory status of a particular drug or device does not have a direct correlation to the material risks of using

that drug or device. To the contrary, there are a myriad of reasons that a manufacturer, who has already submitted a drug for FDA approval for one type of cancer, will decline to engage in the time, effort and expense associated with re-submission for approval on another type of cancer, particularly when it is common medical practice to utilize drugs/devices in an "off-label" manner in this country. [14] A physician better serves his patient by keeping abreast of the medical literature and the standards in the medical community, and generating a proper informed consent discussion with a patient based upon the known material risks, complications, benefits and alternatives to a particular treatment. Ironically, Respondents pray this Court will dispense with the very "professional standard" that best serves the patient populous. Sound public policy demands this Court rule otherwise.

*24 CONCLUSION

In conclusion, the trial court's preclusion of Dr. Trovato's testimony and its evidentiary rulings below were proper and well within its broad discretion. The Court of Special Appeals erred in finding that the trial court **abused** its discretion, in determining that any error was not harmless, and in vacating the judgment in Petitioners' favor. Petitioners request that this Court reverse the judgment of the Court of Special Appeals and reinstate the judgment in Petitioners' favor.

Furthermore, given that the Court of Special Appeals correctly held that the pharmacist, on remand, could not provide testimony "regarding the nature of the material risks associated with the particular regimen of treatment... and any alternative treatment options," there is no basis upon which the judgment in Petitioner's favor should have been vacated. Without any testimony, whatsoever, on the material risks associated with the treatment regimen proposed by Dr. Shannon, Respondents failed to adduce the requisite evidence to sustain an informed consent action, a failure that will linger on remand. Furthermore, given that Respondents did not and cannot adduce any evidence of material risks to the Amifostine, any evidence that was impermissible excluded by the trial court is harmless as a matter of law.

To the extent that the trial court erred, it did so in denying summary judgment and/or judgment on behalf of Petitioners given that Respondents' case was void of any evidence that Dr. Shannon failed to disclose a material risk to Mr. Fusco in obtaining informed consent. Even if this matter is remanded due to some error below, this Court should remand with instructions to enter judgment in favor of Petitioners given that Respondents continue to lack the necessary evidence to support a prima facie case of lack of informed consent.

Regardless of the avenue, the Court of Special Appeals mandate should be reversed and judgment in favor of Petitioners reinstated.

Footnotes

1 In another area of their Brief, Respondents claim that Dr. Trovato would opine on "tthe nature of the risks inherent to Amifostine, probabilities of therapeutic success, frequency of occurrence of risks, and nature of available alternatives..." Furthermore, the heading of their Argument Section I provides: "The Court of Special Appeals Properly Reversed the Trial Court's Ruling Because Dr. Trovato is Qualified to Provide Expert Testimony Concerning the Material Risks of Amifostine in an Informed Consent Case and his Exclusion was Error." Thus, Respondents contradict themselves in their Brief to this Court, and in that light, appear to disregard the Court of Special Appeals' express limitation. Quite frankly, to the extent Dr. Trovato is offered for opinions on material risks, those would constitute new opinions never disclosed in discovery, particularly given that Dr. Trovato testified that he didn't know what a material risk to Amifostine was. [E.143].

2 In Brief to this Court, Respondent argues that an expert should simply provide general medical information to the trier of fact so that a jury can determine what risks and information are material. See Resp. Brief, pg. 16.

3 Ironically, in other portions of their Brief, Respondents appear to concede that expert testimony is not disposed of completely and state that expert testimony is needed to establish "nature of risks inherent to treatment...." See Resp. Brief, pg. 16. Ironically, this is the very testimony which the Court of Special Appeals expressly precluded Dr. Trovato from giving on remand. Given Respondent's concession that expert testimony in this area is required, they are hard pressed to deny the void in their own case on remand.

4 Respondent's only response to the clear requirements of Section 3-2A-02(c)(1) is to declare that informed consent does not constitute "care given by the health care provider." See Resp. Brief, pg. 17. This is nonsensical. Providing a patient with information about various proposed treatment options is a necessary and pivotal component of health care, without which medical treatment could not be provided. The Legislature did not exempt informed consent claims from the mandatory health care arbitration process, and therefore, clearly considers informed consent a component of health care. In so doing, the Legislature provides for a professional standard for liability determinations which, as applied to informed consent, would demand that informed consent discussions be consistent with the standards in the medical community.

5 That is not to suggest that expert testimony is required in every informed consent action; it is conceivable that there will be cases where the void in information disclosed is so obvious that laypersons need no elucidation by expert testimony. Expert testimony cannot be dispensed with, however, in cases like Mr. Fusco's where complex oncologic patients are being treated in a multifaceted manner (radiation, hormone therapy, drugs), and the particular drug at issue - Amifostine - is not a drug commonly utilized by members of the populous. Additionally, the alleged resulting injury to the patient was one of the most rare diseases and occurrences: the undisputed testimony in this case established that the risk of SJS or TENS from Amifostine is between 6-9 cases per 10,000, for a statistical rate of 0.06 to 0.09. [E.1531-33,1547-48].

6 Respondents attempt to dilute the intermediate court's express limitation on Dr. Trovato's testimony by claiming that Dr. Trovato simply cannot comment upon the "adequacy" or "sufficiency" of Dr. Shannon's informed consent discussion. The Court of Special Appeals' limitation is not so narrow as Respondents' portray; to the contrary, Dr. Trovato is precluded from testifying about "regarding the nature of the material risks associated with the particular regimen of treatment provided to Mr. Fusco and any alternative treatment option." In short- he cannot provide testimony which would fall within "a fact of consequence for the trier" in the context of an informed consent claim, period.

7 Respondents lament having been unable to call an expert of their own at the trial below. See Resp. Brief, pg. 37. The fact is, Respondents were in this position due to their decision to retain a pharmacist vice a physician and due to their failure to elicit testimony that sounded in informed consent vice negligence. It is their own choices, not any alleged errors by the lower court, that created the situation in which Respondents found themselves below and find themselves now on appeal. The old adage that "bad facts create bad law," comes to mind; Petitioners urge this Court to refrain from creating bad law from a case in which the situation at hand could have been avoided had Respondents retained a physician to opine on informed consent, rather than a pharmacist to opine on negligence.

8 As the Brief of the Amici Curie points out, the regulatory history of the precautionary language about the limited testing in the **elderly** is illustrative of the hazards in requiring FDA status to be a component of an informed consent discussion. First, the FDA requested an additional warning on the label regarding the **elderly**, "not because the risks were different for **elderly** patients, as there is no evidence they were, but because the size of the statistical sample was not large enough based on FDA criteria." See Amici, pg. 34 (referencing the FDA approval letter dated March 27, 2003, available at http://www.accessdata.fda.gov/grudsatfda docs/appletter/2003/20221slr0171tr.pdf Furthermore, the addition to the label regarding the **elderly** precaution was not in existence at the time Dr. Shannon had his informed consent discussion with Mr. Fusco. That addition was not approved by the FDA until two weeks **after** Dr. Shannon's discussion with Mr. Fusco. *See* Amici, pg. 35. This Court will recall that Petitioners preserved their objection to the use of the package insert on the basis that it post-dated the treatment at issue. [E.540]. The lower court's ruling precluding use of the package insert (and thereby, reference to the warning about limited testing in the **elderly**, was clearly proper.

9 Despite the lower court's ruling that no mention of the warnings on the package insert about **elderly** patients be made, Respondents' counsel argued this point to the jury. [E.911]. Several times in opening statements, Respondents' counsel stated that the medication "had a warning" that it had not been tested for use in the **elderly** and further, that Mr. Fusco was not advised of that warning:

"[T]his medication... has a warning. This should not be used in **elderly** patients. This medication has not been tested in **elderly** patient, Amifostine. Be very careful if you're going to use this medication in **elderly** patients. And neither Dr. Shombert nor Dr. Shannon told Michael or Anthony Fusco that fact. Neither of them told him what the medication said about use with **elderly** patients..." [E.924]

"Was he advised that it shouldn't be used in **elderly** patients and you have to be very cautious because we don't know the effects of this in **elderly** patients?" [E.929]

"Did he ever tell you... that there are precautions saying it hasn't been tested in **elderly** patients? No, he never told us that... Let me tell you this. The fact...that there are strong precautions for use in **elderly** patients is not disputed.... Everybody agrees that he was never advised that this mediation has not been properly tested for use in **elderly** patients... Never told that." [E.934].

Thus, in spite of the court's ruling precluding counsel from utilizing or mentioning the package insert in opening statement, Respondents' counsel, within minutes of that ruling, did precisely that.

10 Amifostine had been approved as a "radiation protectorate" for other types of cancer, including head, neck, ovarian, and kidney cancer; regarding prostate cancer, however, the drug was in the second phase of clinical trials.

11 The fact that Dr. Shannon disclosed the off-label use of the drug to Mr. Fusco doesn't create a factual predicate, unless or until Respondents adduce a qualified expert witness to testify that the disclosure of off-label use was a material risk requiring disclosure

in an informed consent discussion. The trial court excluded this testimony due to the potential confusion it would cause the jury and prejudice that would result from inserting into evidence testimony about "approved uses" when the sole issue before the jury was informed consent, not malpractice. This evidentiary determination was well within the trial court's broad discretion.

12 Furthermore, there is no evidence that SJS/TENS developed in Mr. Fusco because he took the drug in the presence of prostate cancer. See Lipscomb, 733 F.2d at 738.

13 Respondent's attempt to further distinguish their "proffer" from the insufficient proffer in *Waldt II*, by noting that *Waldt II* made no proffer as to the "risks inherent in the use of the nuerofor's stent, probability of success, frequency of risks, or available alternatives." Ironically, those areas of testimony which the Waldt II proffer lacked and Respondents claim to provide, are the very areas of testimony on which the Court of Special Appeals expressly prohibited Dr. Trovato from testifying.

14 *See* Amici, pgs. 36-37 (citing studies which demonstrate anywhere from 21% - 36% of drugs used are for off-label purposes).

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